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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,073	04/08/2002	Brian Nielsen	P67699USO	6930

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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 01/14/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,073

Applicant(s)

NIELSEN, BRIAN

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-13 is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

1. The preliminary filed on 4/8/02 has been received and made of record in the application file wrapper. The specification has been amended to include the priority data, and claims 3-11 have been amended.

Information Disclosure Statement

2. The information disclosure statement filed 10/15/02 has been received and made of record in the file wrapper. Note the acknowledged form PTO-1449 enclosed herewith.

Specification

3. The disclosure is objected to because of the following informalities: the **Brief Description of the Drawings** section is missing from the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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5. Claims 2-5, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation less than 1000 cP, and the claim also recites more preferred less than 500 cp, even more preferred less than 300 cP and most preferred 40 to 200 cP, which is the narrower statement of the range/limitation.

Claim 2 is indefinite in that the examiner is unclear as to which limitation is present in the claim, the broad range, the more preferred range, the even more preferred range or the most preferred range.

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The applicant should also note that claims 3, 4, 10 and 11 have similar recitations, which equate to range within a range indefiniteness.

As regards claim 5, the claim is indefinite in that the examiner is unclear as to whether or not the applicant is claiming the solvent as a positive limitation. Since a solvent has not been positively recited, the applicant is not allowed to further limit the solvent. Additionally, the examiner has assumed that the solvent is not intended to be positively recited in claim 1 where it is first introduced and is therefore not given patentable weight in claims 1 or 5.

Additionally, the applicant note attempts to further limit subject matter, which has not been positively recited, renders the claims are indefinite in that the examiner is unclear as to whether a combination claim is sought. More specifically, the applicant in claims 5, 6, 9, 10 and 11, attempts to further limit the acid, the temperature range of the heat treatment, the solvent and the ratio of acid to chitosan; however, these features have not been positively recited.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/46818 ("Court").

As regards claim 1, Court discloses knitted wound dressings (wound care devices) comprising a mixture of swellable, gel forming chitosan fibers (abstract, page 4, line 31-page 5, line-line 25. As regards applicant's recitation "having been modified by treatment with acid in a solvent which is not able to dissolve the chitosan fibers and by treatment with heat", the examiner contends that the method by which the fibers are formed is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

As regards claim 4, note the absorption rate disclosed on page 5, lines 26-30.

As regard claim 6, the chitosan fibers are **capable** of having been heat treated with heat in the claimed temperature range. Applicant should note that the method of how the fibers are modified is of no consequence in a product claim.

As regards claim 8, other fibers are used and are present in the claimed range (page 3, line 31-page 4, line 4).

As regards claim 9, the acid is capable of being a mixture of acids. Again the applicant should note that the method of how the fibers are modified is of no consequence in a product claim, and the fibers are capable of having been treated by a mixture of acids.

As regards claims 10 and 11, the ratio of acid to chitosan is **capable** of being within the claimed range. Again the applicant should note that the method of how the fibers are modified is of no consequence in a product claim.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,599,916 ("Dutkiewicz et al.").

As regards claim 1, Dutkiewicz et al. disclose absorbent chitosan fibers capable of swelling and gelling. The fibers, as disclosed by Dutkiewicz-et al., are for use in wound dressings (wound care devices). As regards applicant's recitation "having been modified by treatment with acid in a solvent which is not able to dissolve the chitosan fibers and by treatment with heat", the examiner contends that the method by which the fibers are formed is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

As to applicant's recitation of a wound care device, Dutkiewicz et al. disclose that the chitosan fibers are for use in wound care devices. Therefore, it would have been

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obvious to one of ordinary skill in the art to manufacture a wound care device using the absorbent fibers disclosed in Dutkiewicz et al.

As regards claim 2, note col. 5, line 46-col. 6, line 25.

As regards claims 4, note col. 7, lines 30-47.

As to claim 5, Dutkiewicz et al. disclose hydroxy acid, which is capable of being soluble in glycolic, glyoxylic, pyruvic, lactic or a hydroxy prionic/butainic acid.

As to claim 6, note the heat treatment disclosed in col. 14, lines 47-52.

As to claim 7, the examiner contends that one having ordinary skill in the art would have found it within the level of ordinary skill in the art to manufacture the fibers of Dutkiewicz et al. in the form of an island dressing or any other type of dressing depending upon the intended use.

11. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Court.

As regards claim 3, Court fails to teach that the proportion between length and diameter of the fibers is at least 24, more preferred more than 80 and most preferred more than 200. Absent a critical teaching and/or a showing of unexpected results derived from the use of fibers characterized in that the proportion between length and diameter of the fibers is at least 24, more preferred more than 80 and most preferred more than 200, the examiner contends that the selection of the length and diameter of the fibers is an obvious design choice.

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As regards claim 7, Court discloses the fibers are manufactured into a knitted wound dressing. Court fails to explicitly state that the wound dressing is an island wound dressing. However, the examiner contends that one having ordinary skill in the art would have out of necessity constructed any type of wound dressing, island or otherwise, and such would have been an obvious design choice within the level of ordinary skill in the art.

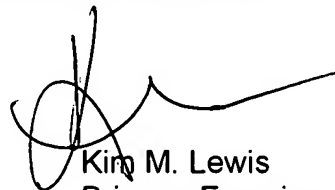
Allowable Subject Matter

12. Claims 12 and 13 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml